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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/761,143	NAIR ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,15-18,27-30 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 15-18, 27-30 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6, 15-18, 27-30 and 34-36 are pending in this application and were examined on their merits, claims 35 and 36 being newly added in the most recent reply submitted by Applicants on 7/25/08.

Applicants' amendments to the claims which specifically delete wherein the cyanidin is isolated and mixed with an anthocyanidin has overcome the previous rejection made under 35 USC 112 First paragraph for lacking written description. However, a new rejection under 35 USC 112 First paragraph is made *infra*.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

Claims 1, 3-6, 15-18, 27-30 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 newly recites: "...(b) inhibiting the enzymes using the dried mixture so that the anthocyanin is hydrolyzed to the cyanidin." This language is New Matter in that this language cannot be found in the original disclosure as filed. While the Instant disclosure teaches that "anthocyanins are hydrolyzed in the gut of a mammal to cyanidin and other compounds" (see [0061] of the specification as published in Applicants' Patent pre-grant publication of this case, US 2001/0002407 A1), the disclosure does not teach that inhibition of the enzymes *causes* hydrolysis of anthocyanin to cyanidin. Applicant is asked to either point out where in the Instant disclosure as filed this information can be found or to delete the new matter or amend 1 accordingly in order to overcome this rejection.

Because claims 3-6, 15-18 and 35 are dependent upon claim 1, claims 3-6, 15-18 and 35 necessarily possess all of the limitations of claim 1 and therefore also contain New Matter and are properly rejected under this statute for containing New Matter.

Claim 27 has been newly amended to recite: "A method for inhibiting inflammation by inhibiting cyclooxygenase or prostaglandin H synthase enzymes in the gut of a mammal..." This statement is New Matter because the Instant disclosure as filed did not explicitly or implicitly teach that cyclooxygenase and prostaglandin H synthase enzymes were inhibited *in the gut* of a mammal. The only mention of the gut

of a mammal in the original disclosure as filed is where Applicants explain that anthocyanins are *hydrolyzed in the gut* of a mammal to cyanidin.

Claim 27 also newly recites: "….(b) inhibiting the inflammation in the gut of the mammal using the dried mixture, so that the anthocyanin is hydrolyzed to the cyanidin in the gut of the mammal." First 'inhibiting the inflammation in the gut' is New Matter. There is nowhere in the original disclosure as filed which discusses treating inflammation of the gut of a mammal or any other organism. Secondly, while the Instant disclosure teaches that "anthocyanins are hydrolyzed in the gut of a mammal to cyanidin and other compounds" the disclosure does not teach that inhibiting inflammation *causes* anthocyanin to hydrolyze in the gut. In other words, Applicants are now claiming that it is the inhibition of inflammation which *causes* hydrolysis of anthocyanins in the gut and which is not found in the original disclosure as filed. Applicant is asked to either point out where in the Instant disclosure as filed this information can be found or to delete the new matter or amend 27 accordingly in order to overcome this rejection.

Because claims 28-30 and 36 are dependent upon claim 27, claims 28-30 and 36 necessarily possess all of the limitations of claim 1 and therefore also contain New Matter and are properly rejected under this statute for lacking Written Description.

Claims 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 35 and 36 serve to narrow claims 1 and 27 respectively to wherein the food grade acid is ascorbic acid. However, claims 1 and 27 both state "with an added food grade acid to prevent decomposition of the dried mixture."

The Instant specification teaches that ascorbic acid is added to the dried anthocyanin-containing powder in order to prevent decomposition (see [0058]) for example. However, at the time the Invention was made, ascorbic acid was known in the art to *promote degradation* of anthocyanins (see for example, col. 1, lines 30-40) and Applicants do not provide any evidence in the Instant specification which contradicts this knowledge. Therefore, claims 35 and 36 are not enabled because it is deemed that ascorbic acid will not perform the intended function of the food grade acid as explicitly stated by claims 1 and 27 respectively.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 15-18, 27-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryglewski et al. (1987) in view of Lietti et al. (GB 1,589,294) in

view of Lenoble et al. (US 5,908,650) in view of Brenner (US 5,462,932 A) in view of Roy (US 4,712,310 A) in light of Wang et al. (1997).*

Inter alia, Applicants have amended claim 1 to include:

(b) inhibiting the enzymes using the dried mixture so that the anthocyanin is hydrolyzed to the cyanidin.

First, 'inhibiting the enzymes' is an inherent consequence of ingesting anthocyanins and cyanidin. Secondly, 'so that the anthocyanin is hydrolyzed to the cyanidin' is also a 'consequence' of apparently inhibiting the enzymes as it is recited by the claims, although as stated above under the 35 USC 112 First rejection, the specification teaches nothing of where hydrolysis of anthocyanins is the result of inhibiting cyclooxygenase or prostaglandin H synthase; rather, the specification teaches that hydrolysis is achieved when the anthocyanin reaches the gut of a mammal. In either respect, the way this new limitation is read into the claim merely states a consequence of the method itself. In other words, this limitation is not an actual method step and does not materially change the method for administering a dried, powdered mixture comprising cyanidin and anthocyanin and does not impart patentability to the claimed method because this newly added limitation does not set the claims apart from the prior art, nor does it render this rejection obviated.

Applicant has further amended claim 1 to require that the mixture is 'powdered.' However, this limitation has been previously rendered obvious via the incorporation of Roy (US 4,712,310 A) who taught that lyophilization of drugs was routine in order to facilitate their incorporation into tablets (see the non-final Office action of 11/06/2007 for example). The act of lyophilizing naturally results in a powder. See for example, Wang et al. (1997) provided in the IDS of 1/16/01 by Applicants: "The adsorbed pigments were then eluted with methanol…[t]he red methanolic solution was concentrated…*in vacuo*, and the aqueous solution was *lyophilized to yield an amorphous red anthocyanin powder*…." (p. 2557, column 1, emphasis added).

Additionally, Applicants have amended claim 27 to require that the anthocyanidin is hydrolyzed to the cyanidin in the gut of the mammal. This also is an intrinsic consequence of ingesting an anthocyanin, and would be *expected* by one of ordinary skill in the art.

Applicant argues "[t]he cited prior art does not recognize that the natural acids and sugars have to be removed from the dried, powdered mixture to prevent hydrolysis of the anthocyanin in the composition…[i]t is counter intuitive to add back to the composition and food grade acid which can hydrolyze the anthocyanin to cyanidin, such ad ascorbic acid..." (p. 8, Remarks). However, Applicants are respectfully importing limitations from the specification into the claims. The prior art teaches the advantageous nature of adding cyanidin and anthocyanidins in a pure or isolated state.

The cyanidin and anthocyanidin of the prior art are in pure (isolated) form and hence, do not contain acids or sugars. "with natural acids and sugars removed" merely indicates that regarding the composition being administered, there are no natural acids and sugars which would be natural to cherries. The prior art teaches that both cyanidin and anthocyanidin can be isolated. The outstanding rejection placed by the examiner is built on the premise that the ordinary artisan would have been motivated to combine cyanidin and anthocyanidin because both of these compounds were known to inhibit cyclooxygenase. In combining these two compounds (isolated) the composition would be void of sugars and acids from a cherry. The motivation to add a food grade acid to a composition comprising anthocyanin and cyanidin is clear from Lenoble et al. (see non-final Office action of 4/29/08).

Applicants further argue that "[[t]he method claims call for hydrolyzing the anthocyanins. There is now way that one skilled in the art could combine Lenoble et al., dealing with stabilizing anthocyanins, with the previously cited references to render the presently claimed method obvious…Applicants' method uses both cyanidin and anthocyanin with the food grade acid, which is not suggested by the prior art" (p. 9, Remarks).

Hence, Applicants' arguments are respectfully not found convincing to overcome this rejection. As discussed previously, hydrolysis, as it is placed in the claims, is merely a consequence of ingesting the anthocyanin. It is clear from Lenoble et al., as

explained in the previous Office action, that one would be motivated to add rosmarinic acid to anthocyanins to stabilize the anthocyanin/cyanidin mixture *prior to ingestion* and therefore *prior to hydrolysis* to maintain the stability of the anthocyanins (see, for example, pp. 4-5 previous Office action).

*this reference is cited merely to relay an intrinsic manifestation of lyophilization and is not used in the basis for this rejection *per se*.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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